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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,972	01/23/2004	Mark David Fidock	PC10960B	8280

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER

LI, RUIXIANG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,972

Applicant(s)

FIDOCK, MARK DAVID

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

RESPONSE TO AMENDMENT

Status of Application, Amendments, and/or Claims

Applicants' amendments filed on 03/07/2005 has been entered in full. Claims 1 and 4-20 are pending. Claims 1, 4-8, and 10 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Rejections and/or Objections

The rejection of claims 7 and 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth at page 6 of the previous office action (11282004, mailed on 11/30/2004), has been withdrawn in view of amended claims.

The rejection of claim 1 under 35 U.S.C. §102(e) as being anticipated by Ramakrishnan (WO200185764-A2, pub. Date: November 15, 2001; filing date: May 9, 2001; earliest 102 (e) date: May 11, 2000), as set forth at pages 6-7 of Paper No. 11242004 (mailed on 11/30/2004), has been withdrawn in view of amended claim.

Claim Rejections Under 35 U. S. C. §101

The rejection of claims 1, 4-8, and 10 under 35 U.S.C. §101, as set forth at pages 3-5 of the previous office action (11282004, mailed on 11/30/2004), is maintained.

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At page 6 of Applicants' response filed on 03/07/2005, Applicants argue that the specification has clearly demonstrated a biological function for the PFI-020 polypeptide encoded by the claimed polynucleotide. Applicants submit that, in addition, to the bioinformatics information, which predicts that PFI-020 is indeed a purinoreceptor based upon ligand binding assays which verified that the receptor binds adenosine-based and uridine-based ligands. Thus, the specification does provide a specific and substantial utility for the claimed nucleic acids. Applicants further submit that at the very least, the polypeptide encoded by the claimed nucleic polynucleotide has the well-established utility of encoding a polypeptide that could be used to assay the presence of the adenosine and uridine-based ligands in a sample.

Applicants' argument has been fully considered, but is not deemed to be persuasive because while asserting that PFI-020 nucleic acid sequence encodes a encoding a G-protein coupled receptor whose ligand is likely to be a nucleotide or a nucleotide derivative and that the PFI-020 polypeptide is most similar to purinergic receptors (page 16) and disclosing activation of the PFI-020 polypeptide by various purinoceptor agonists in a FLIPR cell-based assay (Example 5; Figures 3-6), the specification fails to disclose the specific biological functions or any physiological significance of the PFI-020 and fails to disclose a specific and substantial utility for the claimed invention.

Moreover, as noted in the previous office action, the sequence homology of the amino acid sequence of PFI-020 with the purinergic receptors (Fig. 2 and page 16) does not endow the claimed nucleic acids with a specific and substantial utility because members

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of purinergic receptors have diverse structures and biological functions (see, e.g., Harden et al, Annu. Rev. Pharmacol. Toxicol. 35: 541-579, 1995; Bhagwat et al, Eur. J. Med. Chem. 32:183-193, 1997) and the functions of each receptor need to be determined individually. The specification also acknowledges that there are several diverse families of receptors, which respond to purine and pyrimidines (4th paragraph of page 2). Furthermore, the use of the polypeptide encoded by the claimed polynucleotide to assay the presence of the adenosine- and uridine- based ligands in a sample does not identify a "real world" context of use for the claimed invention.

For the above reasons, the rejection of claims 1, 4-8, and 10 under 35 U.S.C. §101 is maintained.

Claim Rejections Under 35 U. S. C. §112, 1st Paragraph (Enablement)

The rejection of claims 1, 4-8, and 10 under 35 U.S.C. §112, 1st paragraph, as set forth at page 5 of the previous office action (11282004, mailed on 11/30/2004), is maintained because the claimed invention is not supported by either a specific, substantial, and credible utility, or a well-established utility, one skilled in the art clearly would not know how to use the claimed invention.

Applicants' argument about the patentable utility of the claimed invention has been fully considered, but is not deemed to be persuasive for the reasons set forth above.

Claim Rejections Under 35 U. S. C. §112, 1st Paragraph (New Matter)

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Amended claim 1 recites an isolated, non-genomic polynucleotide. However, there is no sufficient support in the original disclosure for the negative limitation "non-genomic polynucleotide".

Claim Rejections Under 35 U. S. C. §102 (e)

The rejection of claims 4-8 and 10 are rejected under 35 U.S.C. §102(e) as being anticipated by Ramakrishnan (WO200185764-A2, pub. Date: November 15, 2001; filing date: May 9, 2001; earliest 102 (e) date: May 11, 2000), as set forth at pages 6-7 of Paper No. 11242004 (mailed on 11/30/2004), is maintained.

At page 7 of Applicants' response filed on 03/07/2005, Applicants argue that the polynucleotide of Ramakrishnan, as shown in Figure 1, incorrectly identifies the open reading frame of the P2Y purinoreceptor, both at the N-terminus and the c-terminus, as

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compared to the polynucleotides of the claimed invention. Therefore, Ramakrishnan does not disclose a vector as claimed in claim 4.

Applicants' argument has been fully considered, but is not deemed to be persuasive because while the open reading frame of the P2Y purinoreceptor was incorrectly identified, the nucleotide sequence taught by Ramakrishnan inherently encodes the amino acid sequence of SEQ ID NO: 2 and culturing a host cell comprising an expression vector comprising the nucleotide sequence of Ramakrishnan under suitable conditions would result in expression the polypeptide of SEQ ID NO: 2. Therefore, the reference of Ramakrishnan meets the limitations of claims 4-8 and 10.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875.

The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

Ruixiang Li

Ruixiang Li, Ph.D.

Examiner

May 23, 2005